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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/699,513	10/31/2003	John K. Pratt	6998US02	7849

23492 7590 03/09/2009

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EXAMINER	
PRYOR, ALTON NATHANIEL	
ART UNIT	**PAPER NUMBER**
1616	

NOTIFICATION DATE	DELIVERY MODE
03/09/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Patents_Abbott_Park@abbott.com
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Office Action Summary	Application No.	Applicant(s)	
	10/699,513	PRATT ET AL.	
	Examiner	Art Unit	
	ALTON N. PRYOR	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 December 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-28,30-35,52-57,62-75 and 90-97* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-28,30-35,52-57,62-75,and 90-97* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/16/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's arguments filed 12/3/08 have been fully considered but they are not persuasive. See discussion below.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 72-75,93-97 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The breadth of the claims: The claims are drawn to a method of treating, preventing or inhibiting infection caused by RNA-containing virus comprising administering to patients a benzothiadiazine compound of instant formula I. The claims are drawn to treating, preventing or inhibiting infections caused by RNA-containing virus broadly. The claims do not list any specific infection or infections caused by RNA – containing virus that are treatable by the instant method. The claims also do not list any specific compound or groups of compounds that would be effective at treating specifically claimed infections. Typically structurally similar compounds treat specific infections. The claims suggest that all of the instant compounds claimed can be employed in a method to treat any and all infections caused by RNA-containing virus.

The state of the art: WO 2004058150 teaches that benzothiadiazine compounds, somewhat structurally similar to those claimed, are useful for treating infections such as hepatitis C virus, Dengue, HIV and picornavirus caused by RNA containing virus. Note, WO '150 is drawn to the treatment of specific conditions using benzothiadiazine compounds, whereas instant claims encompass treating all conditions caused by RNA-containing virus with all claimed benzothiadiazine. In addition the state of the appears to lie in treatment as opposed to prevention or inhibition according to WO '150. Therefore, the instant invention is enabled for treatment but not enabled for prevention or inhibition of infections caused by RNA-containing virus.

The level of direction provided by the inventor: The instant specification does not provide any in vivo or in vitro data or working examples with regard to treating, preventing or inhibiting infections caused by RNA virus using instant benzothiadiazine compounds.

The quantity of experimentation needed to make or use the invention: The quantity of experimentation needed is undue. First, an artisan would first have to make a tremendous number of compounds according to claim 25. Second, the artisan would have to determine which compounds would be effective at treating which infection or infection(s) caused by RNA containing virus.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct

from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 25-28,30-35,52-57,62-75,and 90-97 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-21 of copending Application No. 11/777692. Although the conflicting claims are not identical, they are not patentably distinct from each other because both inventions claim similar compounds and methods of treating infections. However the inventions differ in scope from the compounds employed in USAN ‘692. Note the thienyl group in the instant claims represents only a single possible A ring that meets the limitation of USAN claims.

Claims 25-28,30-35,52-57,62-75,and 90-97 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3,6,7,15-33,38-41, 58,59 and 62 of copending Application No. 12/098024. Although the conflicting claims are not identical, they are not patentably distinct from each other because both inventions claim similar compounds and methods of treating infections. However the inventions differ in scope from the compounds employed in

USAN '024. Note the thienyl group in the instant claims represents only a single possible A ring that meets the limitation of USAN claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Applicants' Argument

The Examiner acknowledges Applicants' cancellation of claims 58-61 and Applicants' commitment to file terminal disclaimers in the later filed applications '692 and '024. The provisional ODP rejections will be withdrawn when no other type of rejection remains in the application. The compounds are employed in a similar method of treatment.

Telephonic Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALTON N. PRYOR whose telephone number is (571)272-0621. The examiner can normally be reached on 8:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Alton N. Pryor/
Primary Examiner, Art Unit 1616